

**Notice of Allowability**

Application No.

10/734,609

Applicant(s)

SMITH ET AL.

Examiner

M. Franco Salvoza

Art Unit

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to after final amendment filed 1/30/06.
2. ☒ The allowed claim(s) is/are 1-26,28 and 29.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>03/20/06</u> |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>08/26/05</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                               | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                       |
|  | 9. <input type="checkbox"/> Other _____  |

### DETAILED ACTION

1. Claims 27 and 30 were canceled. Claims 1-26, 28-29 are pending and under consideration.

By way of examiner's amendment, the following changes were made:

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Donna Ferber on March 20, 2006.

The application has been amended as follows:

Specification, p. 2:

U.S. Published Application No. 2002-0015945 A1 has been changed to U.S. Patent No. 6,767,699.

U.S. Published Application No. 2001-0016199 has been changed to U.S. Patent No. 6,521,235.

Claim 22 has been amended to read "the method of claim 1," not "the method of claim1."

Claim 1 has been amended to read as follows:

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Claim 1. A method for preparing alphaviral replicon particles (ARPS), said method comprising the steps of:

- (a) introducing an alphavirus replicon nucleic acid into a host cell, said replicon nucleic acid comprising at least a virus packaging signal and at least one heterologous coding sequence expressible in said alphaviral replicon nucleic acid, wherein said host cell comprises at least one helper function, to produce a modified host cell;
- (b) culturing said modified host cell under conditions allowing expression of the at least one helper function, allowing replication of said alphaviral replicon nucleic acid and packaging of said alphaviral replicon nucleic acid to form ARPS, wherein said ARPs are heparin-binding ARPS, ~~and~~;
- (c) contacting the modified host cells after step (b) with an aqueous solution having an ionic strength of from 0.2 M to 5 M to release the ARPS into the aqueous solution to produce a ARP-containing solution and;
- (d) collecting ARPS from the ARP-containing solution of step (c).

Claim 26 has been amended to read as follows:

Claim 26. (Previously amended) A method for preparing alphaviral replicon particles (ARPS), said method comprising the steps of:

- (a) introducing an alphavirus replicon nucleic acid into a host cell, said replicon nucleic acid comprising at least a virus packaging signal and at least one heterologous coding sequence expressible in said alphaviral replicon nucleic acid, wherein said host cell comprises at least one helper function, to produce a modified host cell, wherein said

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replicon nucleic acid is introduced into the host cell by electroporation of host cells at a concentration of from  $5 \times 10^4$  to  $5 \times 10^6$  cells per milliliter;

(b) culturing said modified host cell under conditions allowing expression of the at least one helper function, allowing replication of said alphaviral replicon nucleic acid and packaging of said alphaviral replicon nucleic acid to form ARPS;

(c) contacting the modified host cells after step (b) with an aqueous solution having an ionic strength of from 0.2 M to 5 M to release the ARPS into the aqueous solution to produce a ARP containing solution and;

(d) collecting ARPs from the ARP-containing solution of step (c).

The following is an examiner's statement of reasons for allowance:

The prior art does not disclose the use of the salt wash in methods for preparing alphaviral replicon particles or the claimed concentrations for the purposes of electroporation.

### ***Conclusion***

To be made of record:

Claims 1-8, 11, 22-25, 26, 28, 29 read on similar subject matter of claims 1-9, 11, 12, 13, 15, 26 of copending Application No. 10/735,601.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

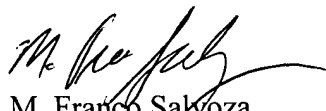
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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
M. Franco Salvoza  
Patent Examiner

  
JAMES HOUSEL 3/20/06  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600